UNITED STATES OF AMERICA

FOOD AND DRUG ADMINISTRATION

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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NATIONAL MAMMOGRAPHY QUALITY ASSURANCE

ADVISORY COMMITTEE

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MEETING

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MONDAY,

APRIL 19, 2004

The Advisory Committee met at 9:00 a.m. in the Walker/Whetstone Room of the Gaithersburg Holiday Inn, Two Montgomery Village Avenue, Gaithersburg, Maryland, Maryanne Harvey, Chairperson, presiding.

PRESENT:

MARYANNE HARVEY, M.S.	Chairperson
JAMES F. CAMBURN, B.S.	Member
E. SCOTT FERGUSON, M.D.	Member
MILES G. HARRISON, JR., M.D	Member

PRESENT (Continued):

JESSICA W. HENDERSON, Ph.D.	Consumer Representative
CAROLYN B. HENDRICKS, M.D.	Member
ANDREW KARELLAS, Ph.D.	Member
MELISSA C. MARTIN, M.S.	Member
CAROL J. MOUNT, R.T. (R)(M)	Member
LINDA S. PURA, R.N., M.P.A.	Consumer Representative
CATALINA R. RAMOS, M.D.	Consumer Representative
AMY R. RIGSBY, R.T. (M)	Member
JULIE E. TIMINS, M.D.	Member
CHARLES FINDER, M.D.	Executive Secretary

FDA PRESENTERS:

HELEN J. BARR, M.D.

MICHAEL P. DIVINE, M.S.

ROBERT PHILLIPS, Ph.D.

C O N T E N T S

P R O C E E D I N G S

(9:01 a.m.)

CHAIRPERSON HARVEY: I would like to call to order this meeting of the National Mammography Quality Assurance Advisory Committee.

I also request that everyone in attendance at this meeting sign in on the sign-in sheet that is available at the door.

I note for the record that the voting members present constitute a quorum as required by 21 CFR, Part 14.

It's nice to see returning members of the committee, and to meet our new members of the committee. I would like us now to introduce ourselves, and we welcome also the members of the public and speakers and people from FDA. Good morning.

Melissa, would you be so kind as to introduce yourselves?

MS. MARTIN: Sure. Now let me get this down so that we can actually talk into it.

My name is Melissa Martin. I'm a medical

physicist running a consulting practice in Southern California. We provide the medical physics services to approximately 200 mammography facilities at this point.

DR. HENDRICKS: I'm Carolyn Hendricks. I'm a medical oncologist in Bethesda.

MS. RIGSBY: I'm Amy Rigsby. I'm a mammographer and the Technical Director for The Rose in Houston Texas.

DR. KARELLAS: I'm Andrew Karellas. I'm a medical physicist and professor of radiology at Emory University.

DR. HENDERSON: I'm Jessica Henderson. I'm a professor of public health at Western Oregon University, and I'm the consumer rep. on this panel.

DR. TIMINS: I'm Julie Timins. I'm a radiologist in Jersey City, New Jersey, and I'm also on my State Commission on Radiation Protection.

CHAIRPERSON HARVEY: I'm Maryanne Harvey. I'm with the New York State Department of Health and Chairperson of this committee.

DR. FINDER: I'm Charles Finder. I'm the

Executive Secretary of the committee. I'm also Associate Director of the Division of Mammography Quality and Radiation Programs, and I'm a radiologist.

MS. MOUNT: I'm Carol Mount. I'm a mammographer, and I'm the supervisor of the Breast Imaging Department at the Mayo Clinic in Rochester, Minnesota.

DR. FERGUSON: I'm Scott Ferguson. I'm a radiologist from Arkansas.

DR. HARRISON: I'm Miles Harrison. I'm an associate professor of surgery associated with Sinai Hospital, a Hopkins affiliate in Baltimore, Maryland.

MS. PURA: I'm Linda Pura. I'm a clinical coordinator for the Cancer Detection Program, Los Angeles County.

MR. CAMBURN: I'm Jim Camburn. I'm Chief of the Radiation Safety Section of the Michigan Department of Community Health.

DR. RAMOS: Catalina Ramos. I am the consumer representative for this committee, and I also am the Director to the Midwest Latino Health Research, Training, and Policy Center at the University of

Illinois.

CHAIRPERSON HARVEY: Thank you.

Dr. Finder will now read the conflict of interest statement.

DR. FINDER: The following announcement addresses conflict of interest issues associated with this meeting and is made a part of the record to preclude even the appearance of any impropriety.

To determine if any conflict existed, the agency reviewed the submitted agenda and all financial interests reported by the committee participants. The conflict of interest statutes prohibit special government employees from participating in matters that could affect their or their employers' financial interests.

However, the agency has determined that participation of certain members, the need for whose services outweighs the potential conflict of interest involved, is in the best interest of the government. Therefore, waivers permitting full participation in general matters that come before the committee have been granted for certain participants because of their

financial involvement with facilities that will be subject to FDA's regulations on mammography quality standards with accrediting, certifying, or inspecting bodies, with manufacturers of mammography equipment, or with their professional affiliations since these organizations could be affected by the committee's deliberations.

These individuals are Mr. James Camburn, Dr. Edgar Ferguson, Ms. Alisa Gilbert, Ms. Maryanne Harvey, Ms. Jessica Henderson, Dr. Andrew Karellas, Ms. Carol Mount, and Dr. Julie Timins.

Waivers are currently on file for Dr. Miles Harrison, Dr. Carolyn Hendricks, Ms. Melissa Martin, Ms. Linda Pura, Dr. Catalina Ramos-Hernandez, and Ms. Amy Rigsby.

Copies of the waivers may be obtained from the agency's Freedom of Information Office, Room 12A-15 of the Parklawn Building.

We would like to note for the record that if any discussion of states or certifying bodies was to take place in any meetings of the committee, it would be a general discussion only. No vote would be

taken and no consensus sought.

In the interest of getting as many viewpoints as possible, all SGEs, including state employees, would be allowed to participate in the general discussion so that all viewpoints could be heard.

In the event that the discussions involve any other matters not already on the agenda in which an FDA participant has a financial interest, that participant should excuse him or herself from such involvement, and the exclusion will be noted for the record.

With respect to all other participants, we ask in the interest of fairness that all persons making statements or presentations disclosed any current or previous financial involvement with accreditation bodies, states doing mammography inspections under contract to FDA, certifying bodies, mobile units, breast implant imaging, consumer complaints, and mammography equipment.

CHAIRPERSON HARVEY: Thank you, Dr. Finder.

Now we will begin committee business. Any committee members have any particular business they would like to raise at this time?

(No response.)

CHAIRPERSON HARVEY: No? All right. We'll move on to the approval of alternative standards.

DR. FINDER: This is Dr. Finder.

For those not familiar with this section of the regulations, which is 900.18, FDA may approve an alternative to a quality standard that occurs under Section 900.12 when the agency determines that the proposed alternative standard will be at least as effective in assuring quality mammography as the standard it proposes to replace, and the proposed alternative is too limited in its applicability to justify an amendment to the standard or offers an expected benefit to human health that is so great that the time required for amending the standard would present an unjustifiable risk to human health, and the granting of the alternative is in keeping with the purpose of the statute.

Since last April's meeting, the division has approved five alternative standards. Two deal with the amount of time a facility has to correct the problem identified during routine quality control testing when using the GE and the Hologic full-field digital mammography units.

The original regulation stated that if any QC test failed in a full-field digital system, the system could not be used until the problem was corrected. These two alternatives, as well as an earlier alternative approved in June 2002, give the facility up to 30 days to correct certain problems that are comparable to the 30-day correction period allowed for film screen units.

And as I said, there were two alternative standards approved. They're available on our Website.

There were also three alternative standards that deal with the use of assessment categories. They are assessment category for post procedure mammograms for marker placement, modification in the assessment categories used in medical reports, and separate assessment categories

for findings in each breast.

These alternative standards basically add two new assessment categories to the six originally listed in the regulations and under certain conditions allow the use of separate assessment categories for each breast.

All of these alternatives in their entirety are available on our Website in the policy guidance help system.

Does anybody have any questions?

(No response.)

CHAIRPERSON HARVEY: Thank you, Dr. Finder.

This begins the section which is the open public meeting. I have a statement I would like to read.

Both the Food and Drug Administration and the public believe in a transparent process for information gathering and decision making. To insure such transparency at the open public hearing session of the Advisory Committee meeting, FDA believes that it is important to understand the context of an

individual's presentation.

For this reason, FDA encourages you, the open public hearing speaker, at the beginning of your written or oral statement to advise the committee of any financial relationship that you may have with the sponsor, its product, and, if know, its direct competitors.

For example, this financial information may include the sponsor's payment of your travel, lodging, or other expenses in connection with your attendance at the meeting. Likewise, FDA encourages you at the beginning of your statement to advise the committee if you do not have any such financial relationships. If you choose not to make the statement of the financial relationships at the beginning of your statement, it will not preclude you from speaking.

Do we have any individuals who would like to come forward? Dr. Reicher.

I think he has got his PowerPoint presentation. This is Dr. Murray Reicher, who is with DR Systems, Incorporated.

Welcome this morning.

DR. REICHER: Thank you very much.

Do I have ten to 15 minutes?

CHAIRPERSON HARVEY: Fifteen minutes.

DR. HENDERSON: Okay. Great. Good morning. I'm Murray Reicher. I'm a radiologist. I practice in San Diego. They may not admit it, but I was trained at UCLA, and I'm with a private group called Radiology Medical Group and also a part owner of some imaging centers in San Diego owned by a corporate entity called Radiology Service Partners.

About 12 years ago I started a PACS company along with another physician, Dr. Evan Fram, and that's DR Systems, and DR Systems today probably has about ten to 20 percent of the U.S. PACS installed base.

So I'd like to present to you -- and funded by all of them. I'm full of conflict of interest. I don't know whether I'm George Plimpton or Zelig, but as a neural radiologist who started off ballooning aneurysms and embolizing AVMs, I've found myself at a very interesting variety of radiology

meetings over the years, this being one of them.

Now, let's see if I can figure out how to get to my next slide.

Okay. So I'm probably stating the obvious to everyone. I don't want to waste your time, but the goals of mammography, as I see it, today are optimization of three factors: accuracy, safety, and cost.

And so I've gone through the literature and examined my own practice and the installed base that we have of about 300 radiology practices and tried to understand better what determines accuracy, safety and cost, and clearly the number one factor is expertise of readers, which is something that this organization often treads lightly on, but I'd like to discuss that a little bit more.

Adjunct technologies, such as computer aided detection, double reading, which I'll call an adjunct technology; we don't get reimbursed the same way for double reading as we do for CAD, but it probably accomplishes about the same thing.

Tech preview; all can improve lesion

detection, but it has a marginal effect relative to the expertise of the initial reader.

Image acquisition technology certain affects quality cost and efficiency of producing mammography. So you may have a device that costs a lot more, but in theory the cost of production per unit mammogram may be equal or less in theory. In reality it's not clear whether that occurs or not.

Required technologies for display, archive, and transportation of digital or film screen mammograms plays a role, and regulation plays a role in determining both cost and quality, and we're here to optimize that as well, and there are other factors.

But I think these are the main factors: the expertise of the reader, the adjunct technologies, the primary image acquisition technology, and what's used to display the mammograms and move them around.

Okay. So what controls those factors, you might ask. Dig a little deeper, and the problem is that the factors that control accuracy, safety and cost are often in conflict with each other, and some just common sense examples so that everybody knows

what I'm talking about, you may use digital technology instead of film screen. Some believes that that improve quality, but it also some believe increases cost. That's a controversial one.

Double reading we know increases accuracy, but it certainly increases cost. You can compress a breast and improve image quality. You can increase radiation and improve image quality, but obviously within reason. There are conflicts there as well. If you compress a breast too much, you could hurt a woman. If you over radiate, that's a bad thing to do. You cause cancers.

Things like data compression may negative impact image quality if over applied, but at the same time can increase access to experts via telemammography. So the problem is that we're all faced with the need to balance off all of these factors that are in conflict with each other, and that the only logical solution is, in fact, to try to obtain a balance, but to do that, you have to weigh each factor appropriately.

So if we focus solely on technical

factors, and the big issue in mammography is expertise to the readers and we have great image quality but unexpert readers, we're really not accomplishing what I think is really the ultimate FDA mandate with regard to quality assurance and mammography.

So I call this mind over matter theory. It's not the theory that says if you don't mind it doesn't matter. It's the one that says that it's what's in the radiologist's head that matter more than technology.

And this wasn't always true, but I think today because of regulation and industry's contribution, we've reached a state in the industry where we have kind of a threshold of technical quality right now both with film screen and digital mammography and possibly even with digitized film screen mammography where the impact of technology has a very small effect or incremental improvements in technology today have a very small effect relative to accessing expertise of the reader.

And I think the big, latent need today in the field of mammography is getting medical images to

those who do the best job reading them.

Digital versus film screen technology, that's been studied and studied, and there's more studies going on, but I hope not to offend anybody here, but the effect seems to be marginal since it is taking a lot of study to prove whether there is any effect in terms of quality, cost, and accuracy between digital and film screen technology.

We all acknowledge that digital is the future, but it would be hard to say that it as a technical factor alone has a big impact. At best it seems to be maybe marginally better quality at higher cost or if you're really busy and efficient, maybe you could drive the cost down.

CAD is the same thing. The benefit of CAD and double reading is anywhere from five to 20 percent, but expert readers do a 200 percent or 150 percent better job than non-expert readers in detecting breast cancer, and that's from a series of published articles that primarily have come out of the academic world. And I think in the private world the variance is even greater.

This is just one of many papers. You guys are familiar with this. So, again, I don't want to waste your time, but this is a paper by Sickles. There are now more recent articles, Beam, Elmore, et cetera.

But this is what all of them are showing, that cancer detection rates for screening among experts in screening mammograms is about six per thousands. In generalists, it's maybe three, three and a half. Recall rates for screening mammograms are significantly lower for experts than they are for generalists. Among diagnostic mammograms, specialists diagnose breast cancer one and a half to two times more frequently.

In this paper, the specialists actually had more call-backs for the diagnostics, but since screening mammograms are much more common than diagnostic mammograms, the overall call-back rate for the experts was significantly lower than the generalists. This is pretty consistent in our literature.

Now, MQSA mandates that we keep data on

our radiologists, but just that we have it, not that we look at it, and that's probably a political issue with the ACR, et cetera, but I pulled some data from a couple of practices that I have a high level of respect for. One of them did 13,000 mammograms in 2003. It's a very good private practice in Southern California. You wouldn't hesitate to go in there as a woman. They're really well reputed.

And their diagnostic cancer detection rates per thousand mammograms read between their readers ranged from 2.6 to 13. So about a 400 percent difference in your chance of having your breast cancer detected depending on whether you show up on a Monday or a Friday there.

Another practice, I took 2002-2003 data. One of them, 26,000 mammograms a year, 15 readers. Each had over 1,000 mammos read. The range was from 1.5 to 13.8 of breast cancers detected per thousand mammos read, and this is a roughly equally distributed group of screening and diagnostic mammograms with the screening mammograms outnumbering the diagnostics about four to one, and in 2002, there was a range of

zero to 23 cancers per thousand mammograms read.

So the variance between physician readers is absolutely enormous and far outweighs any other technical factor.

So given that, I mean, why not the obvious? I mean, why don't just experts read mammograms? What's the deal on that?

And the answer is, first of all, it's completely clinically impractical. In the vast majority of places where mammograms are done today, it's the general three-ring circus of a radiology department. There's MR, CTs, ultrasound, nukes, interventional procedures, lots of other things going on, and mammography is one of many things done at that particular hospital or imaging center, and they can't fund a specialized mammographer. There isn't enough mammo done at any one site to keep anybody busy for more than an hour or two a day.

And so mammography falls to the person who can't do everything else well. Okay? So if you're getting close to retirement and you can't -- sorry, again. I apologize. I'm not feeling any knives in

the back here -- but, you know, oftentimes if you can't do interventional radiology and you don't do MRI and you haven't read a risk MR in a long time, you know, you don't do myelograms, you can do mammograms.

And I'm not saying that -- I'm not insulting the field of mammographers here. Obviously there's great mammographers, but this is a reality that mammography is one of many things done in the typical place where it's provided, and it's just absolutely clinically impractical to have a physician doing only full-time mammography there because they can't be moved around.

Okay, and the next thing is it's just not financially viable. As an imaging center owner, I can tell you that we do mammography at a loss. It actually costs us a little bit more. As hard as we try every year, and we do it a little harder, it costs us about 77.50 to do a mammogram and about $77 is about what we get global for a mammogram in Southern California, and that's based on very large data sets over a period of years in a practice that does mammography in three different locations.

So it's not financially viable. Some may argue it's not financially viable to do mammography at all, but it becomes very difficult if you're trying to do mammography with a subspecialized radiologist.

So the big latent need today in mammography, in my view, is moving mammograms around, and it's not just to get the mammograms in the hands of the experts, but also to get the comparison views, to lower the costs, to reduce the cost of archive. I mean, we have no way of knowing right now just how many unnecessary biopsies are done simply because of the inconvenience involved in getting the old study. So we have to increase the transportability of mammograms.

One way of doing this is to digitize film screen mammograms. That's a tricky way because that depends on the quality of the digitizer and the initial mammogram. It could also facilitate comparison and lower archive cost, and maybe the threshold for primary reading of the digitized film screen mammogram and another threshold for using a film screen mammogram for comparison.

If I'm looking for calcs. and the patient's old mammogram was in Denver, I could wait a week and have the film shipped to me to San Diego, if they even arrive, or if somebody there has a digitizer and I could look at those images in two minutes on the Internet, I may be able to dispose of that woman's problems, and if the calcs. were there before and they're there now, that's good enough.

You know, if they weren't there before, well, maybe I have to go see the original films in order to know that they really weren't there or that the digitizer missed them.

So recall rates and cancer detection rates can be improved through that process. We can increase the use of data compression because today a film screen mammogram is a minimum of ten or I'd say eight meg. and a maximum digitized could be 50 megabytes. No practical way to move it over to the type of lines that are now commonly affording these days like DSL and cable modems without data compression, and these images seem to be quite compressible, well, perhaps without altering image quality. I'll qualify that

statement.

Consider the data requirements. You know, some vendors think a 50 meg. mammo must be better than an eight meg. mammo. If a 50 meg. mammo can't be moved and an eight meg. mammo can, and the eight meg. mammo is read by an expert, you know, I'd like my wife's mammogram read by an expert, not by a non-expert given this data.

And consider soft copy regulatory requirements that promote low cost soft copy reading.

How about data compression? Lossly versus lossless, of course, is not the same as visually destructive versus visually identical. I think the FDA's position is although there are types of medical imaging, you can use lossy data compression and it's up to the discretion of the radiologist.

But mammography is not treated the same way. It's lossless or nothing, and we, I think have some pretty good evidence that you can excess the loss list data compression parameters and end up with images that people find visually indistinguishable.

Consider enabling users and their

physicists to document that data compression was elected at their site and that it doesn't alter image quality in adopting a test for that.

So my time is up.

CHAIRPERSON HARVEY: Yes.

DR. REICHER: I'll just get to my last questions here. The conclusion -- stop. Can I do something here to --

CHAIRPERSON HARVEY: I know.

DR. REICHER: Okay. The conclusion is it's mind over matter here. Improving mammography safety accuracy and cost can best be achieved by enabling and promoting adoption of technologies that increase the probability of reading by experts and a clear and logical policy for film screen mammograms, data compression and soft copy reading is needed.

And then the questions I have that I hope can frame some of the discussion is, first and foremost, when is an image an identical copy because that, if we had one standard way of establishing that an image was an identical copy, that would, therefore, answer the question of when one can digitize and

destroy films, for example, and keep a digital record only; whether one could use lossy data compression or nondestructive loss list data compression and related questions like even if you do degrade the image, what about the comparison study, what about the referring physician image distribution issue.

I'm going to get a referring doctor image over the Internet. Does that also have to be a, quote, perfect image?

Currently I think there's a rule that says I have to give a woman her films. Can I give her a CD instead that has all of the data on it and it started off as a digital image?

And is there an accepted non-film based technique for MQSA? That's local inspectors. You know, what if I don't have film at all? How do you inspect me?

I've gotten sorts of shrugs and not really sure, and you know, the worst torture is not a yes or a no here. It's ambiguity.

So thank you. I hope that's helpful to you.

CHAIRPERSON HARVEY: Thank you very much, Dr. Reicher.

Does anyone have any questions at this time? Lots to think about.

(No response.)

CHAIRPERSON HARVEY: Thank you.

We have one other speaker. Mr. Jerry Thompson -- Thomas. Excuse me. Doctor, representing the Department of Radiology and Radiological Sciences of the Uniformed Services University of Health Sciences.

Good morning.

DR. THOMAS: That's a mouthful, isn't it? Yeah.

CHAIRPERSON HARVEY: How are you?

DR. THOMAS: Good morning. I'm Jerry Thomas. Some of you know me; some of you don't. I'm changing sides of the podium. I was the Department of Defense's representative liaison with this committee when MQSA initially started, and I look at the successes that we collectively have had over the years, and I'm most impressed.

The reason that I'm speaking is that I called and talked with Dr. Finder at the end of last week to find out who was going to be speaking on compression now that that's an issue that's now becoming of interest in mammography.

I had better back up and give you the disclosure, too. I have absolutely no conflicts that are absolute, but there are some potential non-financial, but apparent conflicts. My research effort is right now focused on developing the second generation tomosynthesis system. My research grants and University of Michigan's research grants are paying for that, but we're developing that in conjunction with the General Electric Corporation.

I have also done extensive teaching in imaging physics and mammography with representatives of each of the three manufacturers that currently have approved digital mammography systems, and I also teach a course for technologists for MTMI.

So as a government employee, I'm not compensated for any of that effort, but those are potentially apparent conflicts if someone would say,

"Well, what's this guy doing?"

Well, let me get back to the point of compression. With the tomosynthesis research effort, I've started to look critically at the advanced application.

That's not me. that's what's sitting here. I have no slides for you.

If we start to look at advanced applications, the viewpoint of compression, I think, is to shift. Traditionally when I was putting together PACS systems and designing that within the Department of Defense, we were concerned about two issues. We were concerned about the storage limitations and, therefore, of our storage devices and, therefore, we wanted to compress those data sets.

And, secondly, the image data sets when we were removing them from the battlefield or just doing teleradiology. And both of those initiatives and issues required us to look critically at compression in those settings.

Currently most of the PACS vendors do offer a compression option for data going on to their

archives. Teleradiology data sometimes are or are not compressed.

In the area of mammography, I'm looking at things probably on a different side of the fence, and that is what is the impact of the development of advanced applications in mammography imaging, and what are the data set sizes going to do to our ability to move the data rapidly?

If we look at tomosynthesis, the current systems that I have and Dan Kopans has for a four and a half centimeter breast, we have reconstructed data of about 360 megabytes for a four and a half centimeter breast.

The next generation system is going to have over double that. We're going to have between 720 to 780 megabytes of slice information per breast for a tomosynthesis reconstruction.

We need to look critically at what the issues of compression are and how compression is going to impact those data sets. I look at lossy compression in three different ways.

Normally we think of compression as being

lossless or lossy, and when we say "lossy," people throw up their hands and say, "Oh, my gosh, we have artifacts, and it's dangerous." I think there are three subsets of lossy compression.

The first would be analytically lossless. I've done some analysis of some compressed data and depending on the compression ratio and the compression algorithm, we can have data that have an overall reduction of one or two or a maximum of three counts or values in the pixel.

What we've not looked at critically is what is the impact on the nearest neighbor of that loss. In other words, is there an overall loss which would be like noise in the image as a result of compression, or is there an overall loss in the image that results in the introduction of artifacts or reduction of contrast within the data set.

The second set of lossy compression, a subset, might be considered to be visually lossless. This is a compression algorithm that when we do an ROC study, we display the images and the radiologist cannot see artifacts, but we do know that the data

have been compressed and decompressed, and that compression has resulted in an overall net loss of information in the image.

The last is one that a radiologist that I used to work with came up, and he says, "Well, it's diagnostic lossless. I can see the artifacts in the image, but that's not where I'm looking."

Well, I understand, but I have as a physicist a difficult time understanding how the meaning of diagnostic lossless. At this point in time, no one has done a critical analysis of any of these three subsets of compression. There has been some excellent work that came out of the Sarnoff lab where the model for the visual discrimination model specifically looking at what is the impact of compression on your ability to visualize content. That's some superb work, and they do have an excellent model in this arena.

The initial results of the work that my lab has been doing and others that I've discussed with, I think, show that we can do between an eight to one to a ten to one lossy compression without overall

loss of data that would impact the diagnostic quality of a mammography image.

Some of the factors that this committee and the FDA, I think, have to consider very critically, we already have approved CAD products. What is going to be the impact of compression on those systems?

Compression is not created equally. By that I mean the compression algorithm and the approach to the compression is substantially different. I can achieve the same compression ratio using different algorithms and have substantially different visual results and analytical results on those data sets.

So when someone comes to the FDA and say, "I would like approval of the compression algorithm that is eight to one or ten to one," the real question that needs to be asked is: how are you compressing it, and what is the analytical loss?

I'm thinking about ways to actually measure those. So compression ratios and the analytical algorithms I feel again need to be looked at very critically. The issues that we need to

consider are what part of the image is the artifact or the compression most impacting? Our ability to visualize an object depends, firs to fall, on the surround in which that object is located, and secondly, the size of that object, and thirdly then is the contrast ratio between the object and its background.

Even with compression, we can develop nonlinear transformations to optimize contrast. So we can have lossy information, but we can analyze that data and display it so that the lossy information or the lossy compression appears to be visually non-lossless in terms of its compression.

So I want to just bring those thoughts to your attention and let you know that there are some of us in the research community that have already started to look at these issues, and I know that there's a lot more work to be done.

Thank you very much.

CHAIRPERSON HARVEY: Thank you.

Any questions from the panel?

(No response.)

CHAIRPERSON HARVEY: Not at this time. Thank you.

We are scheduled for a break at this time. However, it's probably a tad early for that. So I think we'll move on to the open committee discussion, which will be the majority of today's meeting, and if it's possible, Dr. Barr, are you ready?

Dr. Barr -- give her a minute to get started here -- she's going to talk about the status of MQSA reauthorization, which question we are all very interested.

Good morning.

DR. BARR: Good morning.

CHAIRPERSON HARVEY: Nice to see you.

DR. BARR: Good morning. Nice to see you, Maryanne.

Good morning. This is Helen Barr. I'm the Acting Deputy Director of the Division of Mammography Quality and Radiation Programs at the FDA. Good morning, everyone.

I think I'll start by explaining that particular fact first. In mid-February, our beloved

office director, Rear Admiral Lireka Joseph passed away, and as the ironies of life would have it after a battle with recurrent breast cancer.

She had just recently been promoted to rear admiral and was able to attend a promotion ceremony about that great event in her life just prior to her death with all of her family attending and by her side.

Excuse me. It's still very hard. Quite an amazing, amazing woman.

Her Deputy, Lynne Rice, moved up into her position on a permanent basis, and we're in excellent hands with Lynne as the office director following in Lee's footsteps and having the privilege of being mentored by Lee over the last couple of years.

John McCrohan, whom most of you know, moved up to take Lee's place as the Acting Office Deputy, and hence I moved up into John's place as the Acting Division Director. So that's where we stand at the moment.

Lynne Rice's position is permanent as the office director. The others are all acting positions,

and we'll see how things shake out as we go along. So I thought I'd bring you all up to speed on that.

Reauthorization. Wow. What can I say? Just for those of you who weren't around at the last meeting, just a real quick update. MQSA expired on September 30th, 2002. There's been a delay in reauthorization that I would characterize as primarily over concern about physician interpretive skill issues alone with several other issues and how to deal with those issues.

We have been able to continue to operate because our inspection and certification authority has no sunset provision. Reauthorization is really the reauthorization of appropriations for MQSA to continue to operate, but our actual authority does not sunset.

Senator Mikulski, who is the primary author of MQSA, originally wanted a portion of the existing CMEs for physicians to be of a self-assessment nature and was trying to get that as a statutory change in reauthorization; that because there were so many issues surrounding that and there wasn't a lot of good data, a compromise -- excuse me.

A bad allergy -- a compromise was made in the Senate, and the Senate passed a two-year reauthorization without any significant change in the statutory requirements as they exist.

Senator Mikulski had also tried to put some studies into that bill that the Senate passed to look at various issues surrounding MQSA, and she was not successful at doing that. So she was able to put them in the labor appropriations bill, and I will quote directly from the bill just so I don't lose any language for you about the different studies that that bill requires to take place.

The GAO office is slated to evaluate the demonstration program regarding the frequency of inspections authorized under the last reauthorization, and I'll be bringing you up to speed on where we stand with that inspection demonstration program, and they are to evaluate the factors that contributed to the closing of approximately 700 mammography facilities nationwide since 2001, whether these closings were due to consolidation or were a true reduction in mammography availability, and to explore the impact on

different subsegments of the population.

You may recall that the GAO a couple of years ago did a mammography access study, and the general conclusion at that time was although there were pockets of the population that may have had some access issues that overall the existing mammography facilities and existing number of units in the United States was able to absorb the capacity for mammography.

And the GAO was also to evaluate the role of states in acting as accreditation bodies or certification bodies or both. We have one state, the State of Iowa, who acts as both a certifier under the states, a certifier program, and as an accreditation body.

Also, in the labor appropriations bill, senator Mikulski was able to add several studies for the Institute of Medicine, and we are currently finalizing our agreement with the Institute of Medicine so that they can begin those studies.

By the way, I should mention those GAO studies are supposed to be in 16 months after the date

that the bill was signed.

The Institute of Medicine studies concentrate on ways to improve physicians' interpretations of mammograms, including approaches that could be taken under MQSA without negatively impacting access to quality mammography.

They are also being asked the question what changes could be made to MQSA to improve mammography quality both in the realm of additional regulatory requirements and also taking away regulatory burden or modifying existing regulations. They state that such reduction or modification in terms of efficiency are important to eliminate disincentives to remain in the field of mammography.

There also are asked to look at ways, including incentives, to insure that sufficient numbers of adequately trained personnel at all levels are recruited and retained, and how data currently collected under MQSA could be used to improve the quality of interpretation of and access to mammography, including identification of new data points that could be collected, other approaches that

would improve the quality of and access to mammography and steps to help make available safe and effective new screening and diagnostic devices. That report is due 15 months after the date of the act.

So that's where we stand with that. The reauthorization bill, although passed by the Senate, is currently in the House and has been sitting there for a while. As I understand it, there is some difference of opinion between the House and the Senate as to how long the reauthorization should be.

Apparently the House favors a five-year reauthorization, and as I said, the Senate's is for two years. So we'll see where we come out, and I have no idea how long it's going to take or when and if it will happen. I certainly hope it will happen this year and timely, March, early on.

I wanted to give you a little bit on our second subject that Dr. Finder had me talking about, the inspection demonstration program and give you a little bit of an update and some very preliminary results from that.

Under the last reauthorization of MQSA,

Congress authorized FDA to perform an inspection demonstration program to evaluate conducting mammography inspections less frequently than annually. In mid-2002, the FDA began an IDP, inspection demonstration program, to assess whether violation free facilities could maintain that status without the scrutiny of annual inspection.

We worked with a number of stakeholders to develop that program, most particularly the Conference of Radiation Control Program Directors.

Approximately 158 facilities ended up being in the group that was going to get to skip an annual inspection and an equal number of facilities ended up in a control group that would continue under the scrutiny of annual inspection. These facilities were covered in approximately 14 states and jurisdictions that agreed to participate in the program.

Our early results show we're not completely finished in inspecting all of the facilities that skipped in inspection. That will happen over the next probably two months. That will

wrap up, but of the group of facilities that have skipped an inspection and then undergone their delayed inspection, if you will, only 58 percent of the study group had no violations compared to approximately 76 percent of the control group.

So those are the early results which at this point seem to say that, you know, annual scrutiny helps facilities maintain a higher level of non-violation. But as I said, these are preliminary results. We need to look at the validity if them and see if the remaining group has the same trend, and we'll be doing an extensive analysis on that. We hop to have results ready during fiscal year 2005, and as I mentioned, the GAO is also supposed to look at that same issue.

Based on these preliminary results, we elected not to extend the program to further cycles and to facilities as soon as the ones who skipped a year get inspected within the next month or two we'll revert back to their annual inspection schedule while we analyze these results.

And the last thing Dr. Finder wanted me to

update the committee on is our program to extend certification to include full-field digital mammography and our approval of the accrediting bodies for digital accreditation.

Originally we had to come up with a plan to be able to use, so that facilities could use full-field digital mammography when it was approved by our Office of Device Evaluation. At that time we had no approved accrediting body. So we developed a program in June 2000 where FDA could extend the existing film screen certificate for a facility to include the use of a digital mammography unit if the facility met certain requirements.

The FDDM had to be located within the same inspection jurisdiction. There had to be a satisfactory mammography equipment evaluation, a list of all personnel who would be using it, and their qualifications, and an annual survey of the unit by an MQSA qualified medical physicist.

And we used that program until we approved accrediting bodies to take over that function.

I'm sorry. In my last minute scramble to

come up here, I may have left one of my papers. I'm sorry. Excuse me.

A number of accrediting bodies applied to us to become accreditors of full-field digital units, and we have now proved two accrediting bodies to perform that function. The American College of Radiology is approved to accredit the GE Senographe 2000, the Fischer SenoScan, and the Lorad Selenia, State of Iowa, is approved to accredit the GE Senographe 2000D and the Lorad Selenia.

The approved units that are out there on the market, approved by our Office of Device Evaluation, are the GE Senographe 2000D, which was approved in January of 2000; the Fischer SenoScan, approved in September of '01; the Lorad Digital Breast Imager, approved in March '02; the Lorad Hologic Selenia, approved in October of '02; and just the latest to join that crowd is the GE Senographe DS, approved in mid-February of this year.

Because of that last approval, which no accrediting body is approved to accredit, we've had to reinstitute our extension of the screen film

certificate so that the folks can use that particular unit.

There are about a little over 500 digital units accredited across the country, spread in about 400 facilities, and I know I always get asked this question. So I got the current number for you. The current number of total certified mammography facilities as of April 1st is 9,079.

And that concludes my update. I don't know if you want me to entertain questions, Charlie, or do you want to move on?

CHAIRPERSON HARVEY: Thank you.

Any questions from the group? Dr. Karellas.

DR. KARELLAS: Dr. Barr, this is Andrew Karellas.

You mentioned about interpretive skills, and that was under the work that is going on, I believe, with the Institute of Medicine.

DR. BARR: That's correct.

DR. KARELLAS: And you mentioned about incentives, and Dr. Reicher just spoke in telling us

that the incentives were not very many. He is actually in the enviable position that he is losing only a few dollars per case. Some of the institutions I worked at would look at it as very successful, meaning losing only a few hundred thousand dollars a year.

So what are we doing in increasing the incentives so that the new radiologists after training are motivated to read mammograms and do all of these things and that way, as Dr. Reicher spoke, that we want people that they dedicate a good part of their practice to breast imaging? That way at least according to the studies they will do better diagnostically.

DR. BARR: Well, we're doing two things, and the biggest is, you know, spending $500,000 that Congress gave us to give to the Institute of Medicine to look at this issue, and allowing them to, with their flexibility, to combine, to call in experts from all around and have the time and the patience and energy to look at this issue.

The second thing we're doing is asking you

all what your ideas and recommendations are for us, and I think that that will probably be discussion later on when Dr. Finder talks about regulations that could be put in place to address some of these issues or things that are in place now that may hinder the retention of physicians.

So those are the two main things we're doing.

One of the reasons, I think, it didn't get put in as part of reauthorization is just as you point out. We don't know the answers to these, and we need experts like you on the panel and experts that the Institute of Medicine can pull together to give us some ideas of how to do that.

And I agree with you. It's a very serious problem. It's certainly one of the reasons I'm standing here instead of practicing mammography.

Does that help?

DR. KARELLAS: Yes. Thank you.

CHAIRPERSON HARVEY: Any other questions from the committee?

(No response.)

CHAIRPERSON HARVEY: Thank you, Dr. Barr.

DR. BARR: Thank you.

CHAIRPERSON HARVEY: Our next speaker is Michael Divine, and he will talk to us on an overview of MQSA inspection findings and post inspection enforcement strategy.

Welcome, Michael.

MR. DIVINE: My name is Michael Divine. I'm with the Inspection and Compliance Branch of the division, and I mostly deal with compliance issue, which is problem facilities, policy relating to how to deal with problem facilities, and resolution of any outstanding noncompliant issues with mammography facilities.

The talk today is going to be about an overview of some important compliance issues that have changed since the last time this committee met. I'm going to talk about some regulatory philosophy involving FDA, and part of that regulatory philosophy involves the use of warning letters.

I'm going to describe what we used to do, which was in effect the last time this committee met,

and a description of what we do now. Most of this has to do with how we use warning letters and how we follow up on inspection problems.

Some of the key features of MQSA are also key features of the way FDA does business is regulating the industries that we deal with, and one of those key factors is a balance between compliance, which is enforcing the law and access to mammography, which we consider very important; in fact, we consider the access to mammography so important that we only use compliance actions or regulatory actions when we think it's absolutely necessary.

And that philosophy carries over in that we emphasize using voluntary correction by the facility rather than using actions to fine the facility or to close them down.

Going over this general philosophy, which as I mentioned covers the entire FDA, allows a firm that is found to have a problem the ability to correct the problem before we take regulatory action. This is based on the fact that we believe that most firms -- and when we talk about mammography, we use the word

"facilities" -- will comply, given the chance, after notification that they have the problem.

And with over ten years of experience in this program, we have come to the conclusion that that has worked very well.

It is also important for us as an agency where we know that if we decide to take a facility on in terms of a regulatory action, that's a very costly endeavor with the facility. It's very costly for us. It's time consuming, and we try to avoid that unless we absolutely need to do that. And so this is part of why the philosophy works.

Now, one of the key features of this voluntary compliance philosophy is something called prior notice. This applies across the board in FDA, and the prior notice philosophy is as long as we notify the key people that we deal with about the problem and we warn them that if they don't fix this problem we're going to take regulatory action, then we believe that in most cases when you deal with ethical people, the problem will be corrected.

Now, actually for about ten years, about

12 years, the most common method that we have used is something called a warning letter. Now, we only use this for a very small percentage of facilities, and it's only for the most serious violations that we find during inspection.

And when we get to talk about the rates of noncompliance, you'll get an idea of how small the number of facilities that actually get warning letters.

A warning letter, obviously, is not appropriate for any situation where there's a danger to health. Obviously that impels us to take action immediately, or whether it's intentional gross or flagrant violations where they're basically obviously not even making an effort to comply or there's something, for instance, that's fraudulent activity at the facility where criminal violations may be involved.

Those are situations where just sending a letter is not really appropriate.

Warning letters have some key features. There has to be an identification of the violations

from the inspection, and so what the facility will see if they get a warning letter is pretty much the same thing that has been identified on the inspection, but at this point they're notified that we considered those violations serious enough that they're getting this letter.

The letter identifies that the violations are serious in nature. It says that failure to correct could result in regulatory action, and the letter lists the type of regulatory actions that they could be subject to. That includes something like a directive plan of correction which would put them under certain obligations to the FDA for a certain period of time. It could be civil money penalties, which could be up to $10,000 per day of violation for each violation. It could be suspension of their certificate, which means they could no longer do mammography.

So all of these things are listed in the letter if they fail to correct the problem, and then the letter asks that they respond within 15 business days after they receive the letter to tell FDA what

they are going to do about it.

In our program, obviously most people here know we have annual inspections of facilities, and our options, as I've already outlined include warning letters. We can also do follow-up inspections, which would be between the two annual inspections where we go in several months after the annual inspection to assure that they've corrected the problems.

And one of the things that we might do is in lieu of sending a warning letter, we might do the follow-up inspection or we would do a follow-up inspection after the warning letter if we felt that it was important enough to check to see that the things identified in the warning letter had been corrected.

And, of course, in situations where a warning letter hasn't worked or it's very serious violations that we think a warning letter is inappropriate, we can take regulatory action. And those regulatory actions, and I've already mentioned some of those already, direct the plans of correction; suspensions, which would actually close the facility; revocations, which would not only take away their

certificate, but the owner-operator couldn't have a certificate for two years after that; civil money penalties, which I've already mentioned; injunctions, which are extremely rare. We have never used them, and that would only be probably necessary in a situation were we had taken away somebody's certificate and they continue to do mammography or they never got a certificate and they refuse to stop when we warn them to stop when we warn them to stop.

The last one, which we consider one of the most key features of this program is patient and physician notification, and that would only be done where we establish that there was a serious risk to human health at the facility, and that's usually through additional mammography review, which is usually done through the facility's accreditation body.

Okay. For many people who have been to these meetings and are familiar with our program, a lot of this is overview, but I wanted to go over it once again because it is specifically involved in the policy and how we approach these different levels of

observations that we find during an inspection.

Level I is a significant violation. This is the one most likely to be involved, for instance, if we take regulatory action or if we were to send a warning letter or do follow-up inspections. There are which we consider the most serious.

The next level down are moderate violations. These usually don't get a warning letter unless we have a history of violations at the facility.

And the last level is ones where we don't generally think that there is going to be a problem unless there is a lot of these or in conjunction with other violations they could compromise mammography quality.

This is just an overview of what's been going on in the last few years, and as you notice on this slide, things are getting better. I think the most telling line on that chart is the light blue line, which is the facilities that have no problems, and when we get into discussing our new guidance on warning letters and dealing with inspection

observations, you'll see that dealing with it differently is going to work out better in the future because I think you can see the facilities are getting better every year. The number of violations is going down. Even at almost all levels it has gotten pretty small.

For those of you who have never been through an inspection or are not familiar with how they're done, all of our inspections are done on computer. We don't have any paper inspections unless the computer is not working.

The inspector goes into the facility, records the data on the computer, and based on what they enter into the computer, the inspection will generate what we call an inspection report, which is basically a detailed list of what the inspector found that had a problem.

It also includes some data that may not be a problem but is included anyway, such as the phantom image score by the inspector, the radiation dose through testing during the inspection, darkroom fog. All of these things are included even whether they're

a problem or not just because we feel it's useful information of the facility to be provided.

But there are identifications by level of all the observations found by the inspector, and then there's something we call important information about your MQSA inspection, which is basically an information sheet that tells the facility where they stand with regard to that inspection and what we expect them to do after the inspection.

If there were serious or moderate level of problems, we're going to ask them to respond to FDA in that document. So it's very important that they read that, though we also try to get our inspectors to make sure that they understand it and they explain it to them verbally so that there's no confusion as to what they're supposed to do.

Once the inspector gets back to their office, they upload that inspection to us. We try to get them to send it to us within five business days. So our inspection database is pretty up to date. In fact, when we go to look at it, when we find out how many facilities had a certain problem, it's pretty

recent. We don't usually have to wait weeks or months to find out what's going on.

Okay. Up until the beginning of our fiscal year, which starts on October 1st, this is basically how we handle the inspection problems. If it was a Level I or they had the same Level II problem for two consecutive inspections, the facility was told during the inspection to correct whatever problems had been found as quickly as possible and that they may get a warning letter.

And the reason we used the word "may" is that in many cases we don't send warning letters because there is some problem with what they found. We disagree with maybe what the inspector found. So it's based on we basically look at everything and we decide, yes, it's a serious problem or it's not a serious problem.

And if it's a serious problem, we send a warning letter. And I would say in the vast majority of situations where you found either Level I or repeat Level I, we did send warning letters, and in that letter we asked for a response within 15 business days

after that inspection.

With a Level II or consecutive Level III problems, we generally wouldn't send that letter, but we still ask for them to respond within 30 business days after the inspection basically explaining to us what they've done to correct the problem, and that doesn't require us to send a letter to the facility. They would send in their corrective action, we would look it over, and decide whether it was okay or not.

And if it was Level III, that was the highest problem that they had, it still goes on their inspection report, but they really don't have to do anything other than correct that as quickly as they can, and if there's a problem, we'll check it during their next annual inspection.

So up until October 1st, this is how we handled inspection observations by policy, and if you look at our history since 1995, 1995 is when we started doing inspections to the present. For the most part we've been sending up to 300 warning letters a year for inspections out of it started off with slightly less than 10,000 facilities. We're down to

about 9,000 facilities.

If we found problems that we thought were of serious concern, such as image quality problems or complaints about quality or where we found a history of violations, we would do something called additional mammography review, which in the vast majority of cases would involve mammograms being sent to the facility's accreditation body for review. They would be evaluated by interpreting physicians to decide whether the quality was a serious risk to human health.

Based on those reviews and some other problems, we've required 14 facilities to notify patients over this time period. For regulatory follow-up, at the same time we've done about 70 follow-up inspections. We've issued five directed plans of correction letters which required facilities to implement things that we directed them to do.

We've fined two facilities with civil money penalties for violations that are ongoing. We have suspended two facilities' certificate, which basically shuts them down, and there are about 98 or

so similar actions to the actions that we take that states have taken under their own laws and regulations.

Some of the problems we had, and a lot of these were internal within the FDA, had to do with the warning letter ratio to the regulatory action ratio, and basically there was concern that we were sending a lot of letters, but we weren't taking a lot of actions, and this was a concern because basically we were sending all of these serious warnings out, and yet it didn't seem that they were always sent for genuinely serious violation.

And example would be a Level I observation might be that the facility had an unlicensed physician. Well, that sounds very significant. However, in the vast majority of situations, most of these were really administrative issues, where they had failed to renew their license. It wasn't based on cause that they have had their license revoked or anything like that, but it had expired and they hadn't taken care to send the forms in to get it taken care of.

Well, it's technically a licensure issue, and we would send warning letters, and those would be resolved by sending in the form. So we didn't consider it to be a significant problem, but internally within the FDA we're sending this very significant letter to the facility, and so they said this is the wrong message to send. You should only send these letter when it's so bad that the next time it happens you're going to close them down or take some serious action.

And for a lot of our history, there have been relatively few enforcement actions for those numbers of warning letters, and so that caused a lot of concern.

Also, a lot of times when we send warning letters it's not the first time that they have had problems. It's that we can establish that there's a history of problems. In a lot of cases that wasn't the case when we sent warning letters.

There was also some concern that warning letters may not be as effective a tool for mammography facilities as they are with other regulated

industries, which could be the drug industry or the device industry, where warning letters are taken very seriously and these companies do everything they can to prevent getting warning letters. I don't think the radiology community really has the same attitude that warning letters that -- I don't know if they take it as seriously as these other industries or not, but we're not sure that the impact it is going to have is going to work as well as it would with these other industries.

And there are other approaches that could be more effective rather than just sending a letter. A facility with a lot of problems, we could go in and do a follow-up inspection before sending a warning letter. At that point we could say, "Well, we found the serious problem, what looked like a serious problem." We'd go back in there and find it still there. Then the warning letter has a lot more meaningful history behind it than just a single problem that might go away on its own just because it was found by the inspector.

So basically here's two columns that

basically lay out what we've done since October 1st, and the big thing is the part that is highlighted in yellow, is basically rather than just taking the Level I problem or a repeat Level II problem and sending a warning letter, what we do is we have sort of changed it more like the Level I and repeat Level III, where we have asked the facility to respond.

Now, the only difference here is that we've changed the response time to sort of match up with the response time for a warning letter. So basically in all of these inspections, Level I, repeat Level II, and repeat Level III, we're asking the facility to respond and tell us what they've done.

And in some of these cases where we have a Level I, but it's quickly resolved and there's not any ongoing problem at the facility, it prevents us from having to send a warning letter where the problem may have already been corrected by the time the letter is sent.

So we believe this is a much better way to deal with an industry that has consistently over the years of the program gotten better and better.

Some of the other steps that we can take -- okay. I think my computer just died. Is it plugged in?

CHAIRPERSON HARVEY: Michael, do you have very many more slides?

MR. DIVINE: I'm sorry?

CHAIRPERSON HARVEY: Do you have many more slides? Would you rather we take a break now?

MR. DIVINE: I have about maybe six or seven.

CHAIRPERSON HARVEY: Okay. So perhaps we'll take a break. Do you think it will be a while before -- that takes the pressure.

MR. DIVINE: That would be fine with me.

DR. HENDERSON: Okay. We're all set.

MR. DIVINE: Oh, we've got it? Oh, good.

DR. FINDER: This is Dr. Finder. Just I want to point out that this change in the compliance strategy or the post inspection follow-up issues was discussed with earlier committee members or earlier committee meetings, and we're basically implementing some of the suggestions that were brought up at those

earlier meetings.

MR. DIVINE: Okay. Now, where was I?

If we have a facility under this new strategy or this new policy that doesn't respond to the Level I or Level II observations, or we find that the response is not adequate, and when I say the response is not adequate, I'm not assuming that they response and we go, "Oh, that's no good," and they do it and then we are going to do something about it.

Basically, if we have an issue, if something doesn't look right or they failed to address all of the problems from that inspection report, we'll probably contact them and call them up and say, you know, "You didn't address the third Level II on this inspection report. Could you address that?" or, "we don't understand what you're doing," or you know, sometimes the quality of the response is not always what we would like to see. So we try to resolve that with the facility.

But if we can't get a decent response out of the facility or we contact them, follow up with them after the inspection and they still don't

respond, then we may decide to do a follow-up inspection or we could decide to send a warning letter.

So based on the facility's response to the inspection rather than just the inspection itself, we will decide on taking some kind of follow-up action.

If we decide, let's say, to do a follow-up inspection based on the fact that we can't get an adequate response from the facility or they just don't respond at all and we go out there and we find continuing problems, we basically have a lot better reasons to send a warning letter rather than just taking the inspection report and deciding on sending a warning.

One, the facility had the problem when we did the inspection.

Two, the facility wouldn't respond or couldn't respond adequately to address the problems.

Three, we went out there and found they hadn't really corrected the problem at all to our satisfaction. Now, we're going to send a warning letter.

So now this warning letter is a much more significant letter, and we're in a much better situation if we decide to take regulatory action based on the fact that the next time we go in there, they're going to have the same serious problem.

If they had been sent a warning letter prior to this, that's another thing I wanted to mention, is that it's our policy in the FDA that if we warned them once, we don't want to have to keep warning them. So we don't keep sending these letters.

The term "paper tiger" comes up when we talk about sending letter after letter after letter while the facility continues to have violations. So our policy is if we send a warning letter, it's supposed to mean something. The next time they have a serious problem, we're going to take some action against them.

Another aspect of this, and this is a significant difference with the follow-up inspection, is when we decide to do the follow-up inspection, it's usually prior to sending a warning letter. It's to see, well, they responded. Then we do the follow-up

inspection, and then we see if they've corrected the problem. Then we decide to send a warning letter.

Once we've sent this significant letter, we're sort of obligated to see, well, we've warned them. Now what are we going to do. And we're not going to in most cases wait until the next inspection, which maybe could be, you know, eight or nine months down the road. Some time within a couple of months after that inspection, we'll go out to the facility and do what we call a compliance inspection and then see have they corrected the problem.

So we're building this history up before we decide to take some serious action, and this compliance inspection. If we have done the follow-up inspection which they got charged for that, they get charged for the annual inspection. We have decided that we're not going to charge them again for the compliance inspection. So this one will be paid for by the FDA.

And of course, if they have continuing problems, we've got a good case that we can take against the facility. If we were to have to go to a

hearing, we could defend. Look, and we could show everything we've done to try to work with the facility, and here we could defend, you know, taking the action when we decide to do it.

So, in summary, we believe this will result in quicker facility response to serious observations, the reason being that if we do the inspection, we have to write the letter. We have to send the letter. We have to wait for the facility response. It could take many weeks before we find out what they're going to do.

In this case we want them to respond within two or three weeks after the inspection. So we're going to get quicker response with this policy.

We believe we get more effective correction motivated by the prospect of a follow-up inspection. We believe that raising the possibility of a follow-up inspection with facilities is more of an incentive. The fact that when we talked about warning letters, many facilities may not take it seriously.

They will take it seriously if they have

to take time off to have another inspector come in there and have to pay many hundreds of dollars to have that inspection, which they could have avoided by just resolving the things after the last inspection.

So we think that's much more of an incentive for them to take this issue rather than having the warning letters. We believe now the warning letters are going to be much more meaningful in the sense that these are really the worst facilities. They're not the ones with the administrative problem or the documentation issue with a couple of technologists. These are people that we have identified as being the worst.

And then once we have identified them, we will warn them, and if they don't correct their problems, then we can take regulatory action against them.

CHAIRPERSON HARVEY: This is Maryanne Harvey.

Michael, are the inspections that are done, the second and the third inspection essentially, are they done by FDA personnel or are they done by the

state people?

MR. DIVINE: The annual inspections, which are kind of surveillance inspections, those are done under state contract with state inspectors. Almost all the other inspections are done by FDA, and one of the reasons is that if we consider it to be a follow-up inspection or compliance inspection, we have identified that facility as, you know, a facility of concern, and we believe that we are in the best position to document those violations if we decide to take regulatory action. We want to make sure that things are done that we don't really have under the state contracts to do.

So basically those are the ones that we want to do ourselves.

CHAIRPERSON HARVEY: Thank you.

Ms. Martin.

MS. MARTIN: Melissa Martin.

I would follow up with a very similar question to what Maryanne asked. Assuming the first inspection is done by the contracted state inspector, it is not infrequent that there has the potential to

be a problem with the inspector's interpretation of a facility's QC program, whatever led to the violation.

On the follow-up inspection, is that inspector part of the process? In other words, you said the second follow-up inspection would be done by an FDA person. Would that same inspector also be involved either for their learning purposes or sine you have an outside person there?

MR. DIVINE: It's possible that the state inspector might go along with the FDA person, but in general following-up inspections, the inspector of record would be an FDA inspector. They certainly would be involved if they didn't go on the follow-up inspection, that they would need to be consulted because if there was any issue with the violation or the observation, we want to make sure that it was done correctly. We want to make sure that that is a real problem.

And in many cases, if there was a problem with the state inspector, for instance, or any inspector, for that matter, where the problem turned out to be a non-problem, we want to correct that.

So we want to make sure that that's avoided. We don't want to do follow-up inspection based on inaccurate information or where the inspector may have made a mistake. In fact, this policy sort of avoids sending the warning letters to those facilities where there is an error because there have been cases where we've had to reverse violations.

So I think that that's not going to really be a problem.

MS. MARTIN: Okay. Well, can I raise one more?

Just the scenario, keep following that scenario. Are there any provisions being developed so that a facility has the equivalent of an appeal? In other words, if they are very unhappy with their review, their initial review, is there a way to request an appeal by a more experienced inspector or an FDA inspector basically to clear their record?

MR. DIVINE: yeah, actually since 1995, we have had a policy in effect that if any observation on inspection is disputed, that's handled at the district office level of FDA. It's not handled at the state.

We do an investigation, basically contact the inspector, contact the facility, analyze whatever information they have available.

If we believe the inspector was correct, we would tell the facility we support this particular problem as being real. If we agree with the facility, we tell the facility that we changed the inspection result, not only send them a corrected report, but we also change the data in the computer so that it doesn't come up as a repeat problem, and we do reverse that.

So we've had this policy in effect, and we have done it in many cases.

CHAIRPERSON HARVEY: Dr. Ferguson.

DR. FERGUSON: Yes. Scott Ferguson.

I've got a couple of questions. One of them has to do with previous administrative things that you say are not as meaningful but may have been listed as a Level I violation. In your new policy, you say, well, if they previously had warning letters, we will look towards regulatory action or we'll look at them more firmly.

Is there any way to look back at previous I don't want to say "meaningless," but administrative violations that may have been a Level I with a warning letter? Are those going to be some consideration for them rather than, you know, two strikes and you're out?

MR. DIVINE: Yeah, to make up a short overview of the regulatory process in terms of when we take regulatory action, and it's pretty complicated. Basically, let's say if a facility got a warning letter a couple of years ago and it was for, let's say, an administrative issue, and I'll use an example where the facility has no documentation on whether a physician is Board certified or had two or three months' training in mammography, which is one of our Level I problems.

So we do the inspection. They don't have that. As a result of that missing documentation, they have a warning letter. They finally were able to get a copy of whatever they need. They send it in. We're comfortable that problem is closed out.

Several years later, a similar problem

comes up with another person at the facility. It's resolved in the same manner. We don't really consider it to be a problem. The fact that they got a warning letter in the past may indicate that this is a facility of concern, but if we decide to take regulatory action against that facility based on that, then we have to basically put a case together. We have to defend it. It has to be cleared by our attorneys. They generally tend to be conservative. They're probably not going to fake that case. If it was on my desk, I probably wouldn't approve it either.

So I don't think that even though we have some warning letters that we may be a little regretful that had been sent years ago, I don't think those letters are going to come back to haunt those facilities because if the case is built based on that kind of a problem, it isn't going to get through our office as being something we're going to take regulatory action against the facility, and hopefully in the future we're not going to be sending letters like that in the future now.

DR. FERGUSON: Very good. Secondly, when

are things supposed to go on the Internet, violations or citations?

MR. DIVINE: We don't post inspection results by facility on the Internet unless they did get a warning letter, and this is not -- the posting of warning letters is FDA policy. It's not MQSA policy, but the Freedom of Information Website of FDA posts all warning letters.

And those are usually posted -- it's hard to tell. It depends on when they -- they send out the warning letter after the inspection, which may be three weeks after the inspection or less, maybe a week. Then they send a copy to our headquarters office for the Freedom of Information. Then they will scan that warning letter, and it will get posted on the Website, and that may take a couple of months.

DR. FERGUSON: Is that all levels? Well, it would be a warning letter. So those are only sent for the most serious problems. So if somebody had a Level II problem, we wouldn't post any information on the Internet about them at all.

DR. FERGUSON: But licensing,

administrative type issues, and I know a facility this happened to with an RT and it was posted, and it was clarified pretty rapidly, but they were told that it had to stay on the Website for one year.

Is that policy? Is that --

MR. DIVINE: I don't know the FDA policy about removing warning letters if there is a policy of removing letters from the Website. Basically we don't have any control over that in our office. Basically our field offices are the ones that send out warning letters.

They're supposed to send a copy to the FOI Office, each warning letter they send, and then that warning letter gets posted.

I will say that any facility that requests that their response to the warning letter be posted, it's FDS policy to post the response as well, but I don't know if there's any policy of removing warning letters.

DR. FERGUSON: I see somebody coming forward. She may address that.

DR. BARR: Yes, this is Dr. Helen Barr.

One other thing we do post, too, which could be what you're referring to is Congress makes us post every year available to the public adverse events or adverse actions that were taken against facilities. We publish all of the actions that we've taken and all of the actions that states have taken that are equivalent to MQSA actions.

And that report goes up, and then is replaced by a current report every year. So it's possible that that's what is being referred to. So that's another way that actions that we've taken are available to the public.

DR. FERGUSON: But is that with a warning letter or is that your whole inspection process?

DR. BARR: That's separate from the warning letter issue. That's actions that we've taken, as Mike identified, like directed plans of corrections requiring facilities to undergo additional mammography review and patient notification, state sanctions that are equivalent to MQSA, any type of action that we've taken against a facility.

It's not specifically, you know, that you

got a Level II violation during your inspection. It's if that rose to an action taken by us or the state.

Does that help?

DR. FERGUSON: That helps. Thank you.

CHAIRPERSON HARVEY: Any other questions from the committee?

(No response.)

CHAIRPERSON HARVEY: Thank you.

I think it's time for our break. Shall we come back at 20 minutes? Five minutes of 11.

Thank you.

(Whereupon, the foregoing matter went off the record at 10:34 a.m. and went back on the record at 11:00 a.m.)

CHAIRPERSON HARVEY: On the record. This meeting is readjourned. We are now on to the area of our meeting today that deals with mechanisms to reduce the regulatory and inspection burden on facilities. These are the directions for discussion which I will read.

"It is almost a decade since the regulations implementing the Mammography Quality

Standards Act were first put into effect. It is therefore appropriate and timely for all the interested parties to review the current program acknowledging the substantial progress that has been made, thanking all the dedicated individuals who worked so hard to improve mammography services and looking ahead to assure that the gains that have been made can be sustained into the future. Congress is in the process of reauthorizing MQSA and has asked the Institute of Medicine to provide it with a report on the current status of mammography and mammography regulation with recommendations for improvement and, in turn, it is the main focus of this committee meeting to identify ways to make the process more efficient and less burdensome for all participants.

In preparation for this meeting, the Committee received documents relating to the current facility regulations, items reviewed during the annual MQSA inspection and the occurrence of inspection violations over the past three years. These same documents were available to the public on our website and as handouts for this meeting. The goal of the

next portion of this meeting is to obtain the Committee's expert opinion on ways to streamline the inspection process and reduce the regulatory burden on facilities while still maintaining or improving mammography quality.

Because this is such a large topic, we will divide it into four subtopics: Personnel; Equipment and Quality Control; Medical Records and Audits; and All Other Areas. Each subtopic will be lead by its own discussion leader. It is anticipated that at the end of this process we will provide the Institute of Medicine with our comments." Do any of the Committee members have any questions at this time? Okay. Excellent. Then we will begin with Personnel issues and Amy Rigsby will be our discussion moderator.

MS. RIGSBY: The Personnel issues are on pages one through five in the Facility Regulations. They are addressed and the Inspections questions on page six through eight. They are quite lengthy, but Personnel deals with the interpreting physicians, the technologists and the physicists. It involves initial

qualifications, their licenses, continuing education, continuing qualification, number of mammograms read, number of mammograms performed by the technologists, but for the physicists number of facilities inspected.

Personally our inspector is great. She comes in. She's there two days. We have two facilities. She makes it very easy for us. Some of the suggestions that I thought about for facilities if they don't already do this is to have everything ready for the inspector when they come - it makes it much easier - and to have everything that we know that's in writing already accomplished.

It's kind of hard for me to understand why someone would know that they are having an inspection and not have current licenses, current things that they know that's going to be looked at because they forgot to renew or they didn't renew. It's just a little hard for me to understand why someone wouldn't do that when they know it's a law, when they know that they need to do that. I know it happens.

Personally I'm not in favor of making a longer time in between inspections. I think one year

is good. We prepare for it all year by keeping up with it. Two years, I think we really would find that there's going to be more violations or more things that aren't kept up with.

People are basically procrastinators. I mean I am too in a lot of things. So if we think we have two years, we're going to wait until just about time for the inspection to make sure everything's all right. Sometimes if we wait too long, then the inspector gets there and we don't have time to get everything done. So a year time, if somebody's not going to keep up with things, at least it's only going to be a year and not two years. This is my personal opinion. But does anyone have any suggestions how the inspection process could be better for facilities? Easier?

CHAIRPERSON HARVEY: Maryanne Harvey. I would play devil's advocate and I would suggest that we look at this from a different viewpoint. We can of course look at each one of these and decide whether or not any particular item is important and they are all important. That's how they got in here initially.

People cared a lot and it was important for us to establish this.

But I would suggest that perhaps what we need to do is come at it from a different viewpoint particularly as it deals with continuing education and interpretative results. I'd like us to move away from looking at all the details and towards an outcome-oriented inspection report that looks at interpretative skills, that looks at the medical audit, that looks at clinical images, that looks at some surrogate like a phantom image.

So I throw out to the group not just how should we look at this. Can we look at this as a changing a dramatic change and what we might recommend, knowing how hard we've worked and knowing from our experience as regulators that it's important to keep people focused on the quality, but also understanding that we need to look ahead for the next 10 years, next 20 years? Mammography is challenged severely and I can't see it getting any better considering how short everyone is of money and how difficult it is for us to be able to get all the

regulations in place and still maintain quality.

One of the issues that came up before that which surprises me every time I hear it is we're down to 9,000 facilities. We have one million additional women reaching the age of 40 which means a lot more people, women who need to be served. As we get older, of course, we need additional services. So I think I'd like to open up to the Committee also an idea that we look at different ways that we might meet qualifications for interpretations other than the ones that are currently in the regulations. Ms. Martin?

MS. MARTIN: Well, I think I'm opening up Pandora's box but I really think it's something we need to think about. You asked us to think about what will change between now and the next ten years. The current scheme is very paper-based. Every facility has to have a hard copy of every piece of paper on every physician, every technologist, every physicist.

I think it is seriously time we go to the age of computerized database so that once a physician -- I will use our example. We have one system, I guess I would call it, that has eight major centers.

There are currently 72 radiologists in that group, 36 of which practice mammography interpretation.

I find it incomprehensible what good it does to require those facilities to have eight separate copies of identical paperwork on the same 36 radiologists. There is some way we need to move into a database so that the radiologist and the technologist have their current CEUs and approved. That should be enough. We ought to have a computer base where the inspectors can go in and find if this physician is current. That should be the end of the questions. We don't need eight separate copies.

And the same would go for the physicists. I cover personally about 100 facilities which means I have to give 100 separate copies of every education certificate I have to those facilities. Somehow we ought to have one database that says this physicist is approved, current and that's the end of the discussion. There's no reason we can't have that.

CHAIRPERSON HARVEY: Do you see that as state created?

MS. MARTIN: No, it has to be national.

CHAIRPERSON HARVEY: National. Yes. Dr. Timins.

DR. TIMINS: Julie Timins. A number of people have discussed the issue of the personnel records with me and I agree that it would be best if there were a centralized record. Whether it would be at the state level, there are some state regulatory agencies or state medical societies who are willing to do this or at the level of a national association such as the American College of Radiology. It doesn't have to have one for all purposes, but there should be the option of a computerized database that is perhaps updated annually. Our main problem is the rolling dates of the inspections and how to deal with that.

CHAIRPERSON HARVEY: Dr. Karellas.

DR. KARELLAS: Andrew Karellas. There is no question about it that we need to move to a computerized form. At the very least, I think inspectors should be able to accept scanned and printed documents if necessary. Potentially there are organizations that they could do that versus putting the burden on the state or Federal Government to

create databases for credentials. I just don't think that's an easy thing to do at the government level.

I believe this is done far better with societies, private contractors, but the FDA and the state governments should either have access or they should be authorized to have an access. Or when the inspector comes, the documents could be presented on the screen one after the other for the inspector to see and a copy should be available. I believe this is a fairly low tact to do that. Even institutions could start that. However, I think the first thing we should do is that we should recommend that this is an accepted way of presenting the data.

CHAIRPERSON HARVEY: Dr. Ferguson.

DR. FERGUSON: Scott Ferguson. I'll just chime in. I agree 100 percent. We need a centralized database and I also agree it needs to be national if possible. I live in a border city and I cover more than one state and to be able to have the information available and not to present it. It always comes up. I have to fax stuff to a facility every time.

The warning letter I talked about earlier

from a facility, I actually had an R.T. who had practiced mammography, had been through several inspections, had one inspector come in 15 years earlier and said "I don't see any documentation of your initial training." She got a level one posted on the Internet and that facility for a year had that posted. If you had centralized credential, it would be very simple to access that information.

CHAIRPERSON HARVEY: Well, certainly, the radiological technologists have theirs centralized. Whenever the state wants to know about whether an individual's licensed, we can just go to that central point and that has worked very well. I don't see that we often have a problem in which it doesn't represent the existing case. Of course, New York now has standard capabilities. Many states do. You can look up whether people are currently licensed and registered. Ms. Martin?

MS. MARTIN: Do the MQSA inspectors honor that? Will they take an on-screen display? I thought it had to be hard copy.

CHAIRPERSON HARVEY: I don't know.

DR. FINDER: This is Dr. Finder. Actually one of the questions that we're going to raise later on in the meeting on Guidance is the issue about scanned documents. I believe that they can accept it. I think we want to go out with some guidance to make it clear that it is acceptable.

The other thing that you mentioned earlier is you needed eight copies of whatever or 50 copies or 100. For facilities in which they have basically the same group that controls them, we have said that they could have one set of books, one set of documentation, and just bring it around for each of the inspections so they don't have to do this. But I think the idea of having this in an electronic format would make it easier to move things around.

Some of the issues -- This is not a new issue about centralized databases and the difficulties. I just wanted to know if the Committee wanted to talk a little bit about at least some of the perceived complications or problems that we have or have thought about trying to centralize these types of systems such as who would have access to it, who could

put in information, how do you identify individuals uniquely. One of our big problems obviously is that people's names are very similar. Even the same person sometimes gets identified by different names at different facilities.

So these are the types of issues that we've thought about in the past and to say nothing of the cost to try and set up a computerized system. There are also privacy issues that would have to be dealt with. The reason that we're basically facility-based in terms of inspections is because the way our law is written, the way our regulations are written and the practicality. We do have an inspector. He's going to be there every year.

However, this is the time, ten years into the program, in which we are looking for new suggestions and ways to do it. Just because we couldn't figure out a better way to do it ten years ago doesn't mean that we can't come up with something better now. So if the Committee wants to discuss not only the advantages which I think everybody recognizes of having a centralized system, but maybe some of the

disadvantages and ways to overcome them, I would be very interested in hearing.

CHAIRPERSON HARVEY: Ms. Mount, did you have something you wanted to say before?

MS. MOUNT: Carol Mount. I just want to comment that our facility has used the Internet to check both technologist's license and physician's license who happen to be out of the country.

CHAIRPERSON HARVEY: Yes. Dr. Karellas.

DR. KARELLAS: Andrew Karellas. The first level would be to make it acceptable for individual facilities or groups of facilities to use a computerized form. I believe that this is the quickest and easiest way to do and as mammography facilities are consolidating as multi-facilities.

As Ms. Martin pointed out if these facilities would digitize or scan their documents, then each facility would be ready all the time and if somebody wanted them, they could be just printed. That does not apply just to the credential issues, but also to QA seeds. There is a huge amount of storage space that is occupied by very heavy folders of all QA

materials and this is putting an added burden on the facilities today.

DR. FINDER: It's Dr. Finder. I want you to keep that in mind because when we come to the afternoon session, we're asking that exact question. What's acceptable? Under what conditions? We don't want to forget that.

DR. RAMOS: Yes. This is Catalina Ramos. I just want to keep in mind all the time. It seems like the electronic records are the best way to go. However, when we talk about access and the majority of us I think come from big facilities and if you go to facilities that are very small places, rural areas, you will see that people do not have all the resources, do not have all the skills.

If you are talking about computers, if you don't have the right computer, most likely you will not be able to store all the documents that you need to have. That is one of my main concerns that when facilities are closed usually they are closed because they are very small, they are in rural areas and they cannot afford the access to be certified or be

recertified and there are more and more women in the rural that will not have access because of this.

MS. PURA: Linda Pura. Is it possible to split the responsibility of the site when it comes to continuing experience versus continuing education? Continuing education for other certifications such as nursing which I'm involved in, we are responsible for our own continuing education records and we maintain them and report those and those could easily as been stated be put into a computer system if that was available. Then, of course, the continuing experience would be onsite information which the facility would have. So can those be split? The responsibilities is something that would be an option.

DR. FINDER: Are you asking me?

MS. PURA: Yes.

DR. FINDER: Everything is open for discussion. I would imagine there are good points and bad points with everything. How are you going to get and who is going to have access for the ability to check people's CME if they weren't issued? How are you going to get that information in?

MS. PURA: I would imagine that would be something that would have to be aligned with the state credentialing offices and most of them are under the Department of Health Services. So there would have to be some sort of an alignment or agreement that it could be done.

DR. FINDER: Right.

CHAIRPERSON HARVEY: Ms. Martin.

MS. MARTIN: Well, again I come back to where do we go in the next ten years. I think we've heard a couple of talks already this morning and Dr. Ferguson alluded to it. I think we have to start thinking of regional or even national interpretation centers as we move into the age where you can send an image anywhere and have it interpreted in any location.

As was said earlier, I would rather have the expert sitting in another state interpret the image than the person who is the inexperienced radiologist. I think we have to look at some method to establish credentials that are accepted nationwide. That's where I was going with this. It's so that